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EXAMINER	
CLARK, AMY LYNN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,150	KIM, SUNG-JIN	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *3-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-8 and 48-54 and the election of Specie A in the reply filed on 8 November 2006 is acknowledged. The traversal is on the ground(s) that Applicant is confused with the above-identified office communication because the Applicant believes that the previous amendment and response replied to every matter indicated in the Office Action, the previous amendment and response elected claims 1,2, 8 and 50, and withdrew claims 3-7, 48, 49, and 51-83. Additionally, the amendment and response "elects species A in Group 1 ", and identifies the claims readable on the elected invention, the Applicant respectfully provides a copy of the paragraph in the previous amendment and response which states this, that "The Applicant provisionally elects species A in Group I. Species A is amended to include limitations substantially different than the Kim (JP 06107555 A) reference indicated by the Examiner. Claim 2 reads upon the elected species A of claim 1, and wherein claim 2 adds an additional element to cover certain aspects of species A. Claim 8 reads upon species A of claim 1, and since the Examiner makes no mention or restriction of claim 8, the Applicant believes claim 8 to read upon the elected species. Claim 50 reads upon species A of claim 1, and wherein claim 50 further limits the elements of species A" and that the Examiner states that "Applicant must elect one method of extraction from Claim 3, Claim 4, Claim 5 or Claim 6 as Specie B." Applicant further argues that the Applicant respectfully believes the Examiner is in error since the previous amendment withdrew claims 3-6 and that the Applicant would like to point out the Examiner's statement in the

previous office action "Applicant is required, in reply to this action, to elect a single species". Applicant further argues that with this statement in mind, there is some confusion in the Examiner's present office communication wherein the Examiner states that the "Applicant must elect one" of Species B (claims 3-6) and C (claim 7). It can be appreciated that one would be confused since the previous amendment and response elected Species A and withdrew all the claims toward non-elected species. If the Examiner will allow Species B and C into the application, then a statement of such is respectfully requested. Applicant further argues that additionally, the Applicant would like to point out that commonly owned patent (US 7,078,065), which issued on July 18, 2006, was allowed with similar species that the Examiner has presently restricted, it is therefore believed that withdrawn claims 3-8, 48-54, and 75-80 are linked to a single general inventive concept of claim 1 either directly or through claim dependency and the provisional elected claims 1,2 and 50 are related and linked to the withdrawn claims 3-8, 48-54 and 75-80 in that all the groups of invention are directed towards the composition in amended claim 1 and claim 3 which depends upon claim 1. Claims 3-8, 48-54 and 75-80 only adds limitations to the common invention in claim 1, therefore no additional search is required by the Examiner since claim 1 is the parent claim. This is not found persuasive because in response to Applicant's argument that Applicant is confused with the above-identified office communication because the Applicant believes that the previous amendment and response replied to every matter indicated in the Office Action, the previous amendment and response elected claims 1,2, 8 and 50, and withdrew claims 3-7, 48, 49, and 51-83. Additionally, the amendment and response

"elects species A in Group 1 ", and identifies the claims readable on the elected invention, the Applicant respectfully provides a copy of the paragraph in the previous amendment and response which states this, that "The Applicant provisionally elects species A in Group I. Species A is amended to include limitations substantially different than the Kim (JP 06107555 A) reference indicated by the Examiner. Claim 2 reads upon the elected species A of claim 1, and wherein claim 2 adds an additional element to cover certain aspects of species A. Claim 8 reads upon species A of claim 1, and since the Examiner makes no mention or restriction of claim 8, the Applicant believes claim 8 to read upon the elected species. Claim 50 reads upon species A of claim 1, and wherein claim 50 further limits the elements of species A" and that the Examiner states that "Applicant must elect one method of extraction from Claim 3, Claim 4, Claim 5 or Claim 6 as Specie B." Applicant further argues that the Applicant respectfully believes the Examiner is in error since the previous amendment withdrew claims 3-6 and that the Applicant would like to point out the Examiner's statement in the previous office action "Applicant is required, in reply to this action, to elect a single species". Applicant further argues that with this statement in mind, there is some confusion in the Examiner's present office communication wherein the Examiner states that the "Applicant must elect one" of Species B (claims 3-6) and C (claim 7). It can be appreciated that one would be confused since the previous amendment and response elected Species A and withdrew all the claims toward non-elected species. If the Examiner will allow Species B and C into the application, then a statement of such is respectfully requested, please note the following. The Examiner sent out a notice of a non-responsive reply (mailed

10/05/2006) because Applicant had failed to also elect from Species B and Species C. The Examiner regrets any confusion on the part of Applicant, however, the Examiner did request that Applicant further elect from within Species B and C in the previous Office Action.

In response to Applicant's argument that additionally, the Applicant would like to point out that commonly owned patent (US 7,078,065), which issued on July 18, 2006, was allowed with similar species that the Examiner has presently restricted, it is therefore believed that withdrawn claims 3-8, 48-54, and 75-80 are linked to a single general inventive concept of claim 1 either directly or through claim dependency and the provisional elected claims 1,2 and 50 are related and linked to the withdrawn claims 3-8, 48-54 and 75-80 in that all the groups of invention are directed towards the composition in amended claim 1 and claim 3 which depends upon claim 1. Claims 3-8, 48-54 and 75-80 only adds limitations to the common invention in claim 1, therefore no additional search is required by the Examiner since claim 1 is the parent claim. This is not found persuasive because MPEP 1850 (II) states:

> An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

In view of Applicant's claims as written, there are several distinct inventions, which irrespective of contributions over the prior art, should not be examined together. Please note that in accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8 and 48-54, drawn to a composition for protecting brain cells or improving memory; said composition comprising an extract of Liriopsis tuber from about 50 to 500 mg; and at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is talc from about 0.5 to 5.0 mg and lactose from about 50 to 500 mg.

Group II, claims 55-64, drawn to a composition for protecting brain cells or improving memory; said composition comprising an extract of Liriopsis tuber from about 50 to 500 mg; and at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is starch from about 1.0 to 10 mg and magnesium stearate from about 10 to 100 mg.

Group III, claims 65-69, drawn to a composition for protecting brain cells or improving memory; said composition comprising an extract of Liriopsis tuber is about 20 g of isomerized sugar, 5.0 mg of antioxidant, 2.0 mg of methylparaoxybenzoate and about 100 ml of purified water.

Group IV, claims 70-74, drawn to a composition for protecting brain cells or improving memory; said composition comprising an extract of Liriopsis tuber from about 50 to 500 mg; and at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is about 1.0 mg or antioxidant, 1.0 mg of Tween 80 and 2.0 ml of distilled water.

Group V, claim 75, drawn to a method for protecting brain cells against damage caused by excitatory amino acids and oxidative stress in a mammal comprising administering to said mammal a therapeutic amount of an extract of Liriopsis tuber of claim 3, wherein said extract of Liriopsis tuber is administered in an amount of from 0.1mg/kg to 500 mg/kg, and wherein said extract is administered to said mammal via a route selected from the group consisting of oral administration, topical application, sterile injection, inhalation, beverage, food product and rectal administration.

Group VI, claim 76, drawn to a method for inhibiting APMP-induced depolarization of a neuronal cell of a mammal comprising administering to said mammal therapeutic amount of an extract of Liriopsis tuber, wherein said extract of Liriopsis tuber is administered in an amount of from 0.1mg/kg to 500 mg/kg and wherein said extract is administered to said mammal via a route selected from the group consisting of oral

administration, topical application, sterile injection, inhalation, beverage, food product and rectal administration.

Group VII, claims 77-79, drawn to a method for facilitating tyrosine phosphorylation of a hippocampal protein of a mammal.

Group VIII, claim 80, drawn to a method of inhibiting cholinesterase activity in the brain of a mammal.

Group IX, claim 81, drawn to a method of treating neurodegenerative diseases of a mammal.

Group X, claim 82, drawn to a method of preventing or treating dementia of a mammal comprising administering a medicament to a mammal.

Group XI, claim 83, drawn to a method of improving memory of a mammal comprising administering a medicament to said mammal.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 1 and 3, at least, are anticipated by or obvious over Kim (Reference N*, Japan Patent Abstract: JP 06-107555 A; 04/1994, Abstract only). For instance, Claim 1 is drawn to a composition for protecting brain cells or improving memory, said composition comprising of an extract of Liriopsis tuber and a pharmaceutically carrier. Kim teaches a Chinese traditional medicine microcapsule for treating neurosis comprising of an extract of *Ophiopogon japonicus* (which is synonymous with Liriopsis) tuber and lactose. Kim further teaches that the extract of *Ophiopogon japonicus* tuber is obtained by extraction with aqueous ethanol. However, it should be noted that Claim 3 constitutes a Product-by-Process type claims. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227

USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Although Kim does not expressly teach lactose in an amount of 50 to 500 mg and Liriopsis tuber in an amount of about 50 to 500 mg, the composition as taught by Kim, has the same use as the composition claimed by Applicant, therefore the composition is one in the same as the composition claimed by Applicant and it would be merely a matter of judicious selection well within the purview of one of ordinary skill in the art to adjust the amounts of each ingredient. Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so unity of the invention is lacking. (Please note the Election/Restriction requirement was made with respect to the claims submitted on 25 April 2006 and that the claims have since been amended).

The requirement is still deemed proper and is therefore made **FINAL.**

Claims 1-83 are currently pending.

Claims 3-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8 November 2006.

Claims 1 and 2 are under examination.

Information Disclosure Statement

The information disclosure statement filed 27 September 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because Applicant has not provided any references along with the submission of the IDS nor has Applicant provided any English translations of the references along with the submission of the IDS. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

The disclosure is objected to because of the following informalities: please correct "was" in line 8 on page 11 to were.

Appropriate correction is required.

Claim Objections

Claim2 is objected to because of the following informalities: "magnesium steerage" should be corrected to read magnesium stearate. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for improving memory comprising dwarf lily turf (*Ophiopogon japonicus*) and *Rehmannia glutinosa* does not reasonably provide enablement for a composition for protecting brain cells or improving memory; comprising; an extract of Liriopsis tuber from about 5.0 to 500 mg;

at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is talc from about 0.5 to 5.0 mg, and lactose from about 50 to 500 mg; and brown rice, job's tear, barley, glutinous rice, perilla japonica, black bean, black

sesame, *Ganoderma lucidum* (FR) karst, and *Rehmannia glutinosa,* nor does the specification reasonably provide enablement for a composition for protecting brain cells comprising dwarf lily turf (*Ophiopogon japonicus*) and *Rehmannia glutinosa*. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make any invention commensurate in scope with these claims. Please note that the state of the art at the time the invention was made recognizes the combination of dwarf lily turf (*Ophiopogon japonicus*) and *Rehmannia glutinosa* in the form of a preparation of medicine for improving memory as taught by Wang et al., Reference U, CN 1053370 C, Abstract only), however, the state of the art did not recognize a composition for protecting brain cells or improving memory; comprising; an extract of Liriopsis tuber from about 5.0 to 500 mg; at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is talc from about 0.5 to 5.0 mg, and lactose from about 50 to 500 mg; and brown rice, job's tear, barley, glutinous rice, perilla japonica, black bean, black sesame, *Ganoderma lucidum* (FR) karst, and *Rehmannia glutinosa*, nor did the state of the art recognize for a composition for protecting brain cells comprising dwarf lily turf (*Ophiopogon japonicus*) and *Rehmannia glutinosa*.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A composition for protecting brain cells or improving memory; comprising; an extract of Liriopsis tuber from about 5.0 to 500 mg; at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is talc from about 0.5 to 5.0 mg, and lactose from about 50 to 500

mg; and brown rice, job's tear, barley, glutinous rice, perilla japonica, black bean, black sesame, *Ganoderma lucidum* (FR) karst, and *Rehmannia glutinosa* and a composition for protecting brain cells comprising dwarf lily turf (*Ophiopogon japonicus*) and *Rehmannia glutinosa* critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 1 and 2 are not considered to be fully enabled by the instant specification. Please note that the scope rejection is made based upon what Applicant appears to have disclosed in the specification as what the extracts of each plant are meant to be. Since the disclosure is ambiguous, it is hard to tell exactly if Applicant is claiming these ingredients, however, it is clear that Applicant is not enabled nor does Applicant have written description (See above) for the composition as claimed.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent

Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the " written description" inquiry, is "*whatever is now claimed*" (See page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, *i.e.*, "an extract of Liriopsis tuber".

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention". Hence, an adequate written description of

the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, describing a method of isolating a composition comprising a plant extract having claim-designated properties, in the absence of knowledge as to what the material consists of or the source of the material is not a description of the material or a method of making the material. In the instant case, on page 4, lines 15-22, Applicant discloses, "The present invention relates to a composition comprising an extract of Liriopsis tuber for protecting brain cells or improving memory. The composition of the present invention for protecting brain ceils or improving memory, includes a Liriopsis tuber extract by 0.5 to 50% by weight based on the total weight of the composition." However, other than the mere mention on page 1 (lines 5 and 6), page 4 (lines 11 and 12 and 15-19), page 5 (lines 24 and 25), page 6 (lines 1-25), page 7 (lines 4-6 and 10) and page 9, wherein Applicant simply states "an extract of Liriopsis tuber", and pages 18-23, 25 and 26, wherein Applicant simply states a methanol extract of Liriopsis tuber, but does not provide any examples of what exact type of Liriopsis tuber Applicant is using. The specification provides several method of extraction on page 6, lines 1-25, page 10, lines 15-25 and page 11, lines 1-9, however, Applicant fails to adequately describe as to what Applicant defines or considers as an extract of Liriopsis. For example, nowhere in the present specification does Applicant render a definition of the

term "an extract of Liriopsis" nor does Applicant cite an example of this term thereof. Please note that Applicant discloses that Liriopsis tuber is a perennial herb classified into Liliaceae, and *includes Liriope i platyphylla* Wang et Tang, *Ophiopogon japonicus* Ker-Gawl., *Ophiopogon stolonifer* Levi. et Vant., *Mondo japonicum* (L.f.) Farwell and *Liriope spicata* (Thunb.) Lour.", however, Applicant fails to describe which specific genus and species of Liriopsis Applicant is claiming as the Liriopsis extract and which specific genus and species of Liriopsis Applicant has used in Applicant's studies shown in Examples 1-6 (pages 11-18 of the specification).

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, "an extract of Liriopsis".

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial potential for variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of what constitutes "an extract of Liriopsis". The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 1 and 2 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethanopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical as noted in this application. The common name or traditional/ethanopharmacological name may have several different Latin names referring to various genus-species of the plant and it is unclear as to which genus and species Applicant is referring. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Applicant may overcome the rejection by placing the genus-species name of "liriopsis", "brown rice", "job's tears", "barley", "glutinous rice", "perilla japonica", and "black bean" in parentheses after the terms "liriopsis", "brown rice", "job's tears", "barley", "glutinous rice", "perilla japonica", and "black bean". Please make sure to write the Latin name in the proper format, wherein the first word is capitalized, the second word is lowercase and the entire name is italicized.

The metes and bounds of Claims 1 and 2 are rendered uncertain by the phrase "A composition for protecting brain cells or improving memory; said composition comprising; an extract of Liriopsis tuber from about 5.0 to 500 mg; at least one pharmaceutically acceptable carrier, said pharmaceutically acceptable carrier is talc from about 0.5 to 5.0 mg, and lactose from about 50 to 500 mg; and brown rice, job's tears, barley, glutinous rice, perilla japonica, black bean, black sesame, *Ganoderma lucidum* (FR) karst, and *Rehmannia glutinosa*" as claim 1 and "The composition of claim 1 further comprising magnesium steerage from 0.1 to 1.0 mg" as claim 2 because the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition. Furthermore, it is unclear if Applicant is claiming that brown rice, job's tears, barley, glutinous rice, perilla japonica, black bean, black sesame, *Ganoderma lucidum* (FR) karst, and *Rehmannia glutinosa* are additional ingredients or if Applicant is claiming that these ingredients are part of the pharmaceutically acceptable carrier. Finally, it is unclear what Applicant means by "protecting brain cells" and "improving memory". Is Applicant claiming that this composition can help people suffering from memory loss (such as through dementia or Alzheimer's) or is Applicant claiming that this composition will help everyone improve memory? What is Applicant claiming that composition is protecting brain cells from? Is Applicant claiming that the composition can protect brain cells from external injury or alcohol consumption or stress or is Applicant claiming protecting brain cells in another capacity? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Please note that no art rejection has currently been made because the claims are unclear and incomprehensible and, therefore, a proper art search could not be performed. The fact that no art rejection has been made does not indicate that no art exists or that the claims would be allowable if Applicant were to overcome the rejections above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark

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